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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,233	02/19/2002	Huaming Wang	GC567-C1	4433

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GENENCOR INTERNATIONAL, INC.
ATTENTION: LEGAL DEPARTMENT
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EXAMINER	
MOORE, WILLIAM W	
ART UNIT	**PAPER NUMBER**
1652	7

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/080,233	WANG, HUAMING	
	Examiner	Art Unit	
	William W. Moore	1652	

-- The MAILING DATE of this c mmunication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 2,3,8,11-20,23-37 and 39-45 is/are pending in the application.

4a) Of the above claim(s) 8,11-20,23-37,44 and 45 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 2,3 and 39-43 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

Applicant's Preliminary Amendment A, Paper No. 5 filed February 19, 2002, has been entered, canceling claims 1, 4-7, 9, 10, 21, 22 and 38, amending claims 2, 3, 12, 17, 19, 20, 23, 30, and 31, and adding the new claims 39-45. Thus claims 2, 3, 8, 11-20, 23-37 and 39-45 are pending in the application. A Declaration of Inventorship filed with the application indicates that it is a Continuation of application serial No. 09/219,702 filed December 22, 1998, which issued on July 30, 2002, as U.S. Patent No. 6,426,410, made of record herewith. Paper No. 5 fails to perfect Applicant's claim to priority, however, by providing an amendatory statement in the specification that refers to the parent application, or to the patent issuing thereon. In order to avoid the rejections made below over several prior art publications, Applicant is invited to amend page 1, line 1, of the specification to identify the relationship of the instant application to its parent application, the serial number and filing date thereof, and to identify the patent that issued thereon, in response to this communication.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. §121:

1. Claims 8, 11-20, 23-37, 44 and 45, drawn to a polynucleotide capable of hybridizing under high stringency conditions to a polynucleotide having the sequence set forth in SEQ ID NO:1, which encodes a phenol oxidase of *Stachybotrys*, to vectors comprising the polynucleotide, to host cells comprising the polynucleotide, and to a method of use of the polynucleotide in a recombinant method of making of the encoded polypeptide in a host cell, classified, *inter alia*, in class 536, subclass 23.2.

2. Claims 2, 3, and 39-43, drawn to a polypeptide having an amino acid sequence at least 70% identical to that of the phenol oxidase of *Stachybotrys*, set forth in SEQ ID NO:2, classified in class 435, subclass 189.

The inventions are distinct, each from the other, because of the following reasons:

Inventions of Groups 1 and 2 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that

the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. H. Thomas Anderton on June 30, 2003, a provisional election was made without traverse to prosecute the invention of Group 2, claims 2, 3, and 39-43. Affirmation of this election must be made by applicant in replying to this Office action. Claims 8, 11-20, 23-37, 44 and 45 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. §101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. §101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. §101.

Claim 3 is rejected under 35 U.S.C. §101 as claiming the same invention as that of claim 3 of prior U.S. Patent No. 6,168,936 because the claimed subject matters of claim 3 herein and the patented claim are indistinguishable. This is a double patenting rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2 and 39-43 are rejected under the judicially created doctrine of double patenting over claims 1, 2, 41 and 42 of U.S. Patent No. 6,168,936 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent. The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: Claims 2 and 39-43 herein, while having recitations that differ from claims of 1, 2, 41 and 42 of the issued patent, describe a phenol oxidase that falls within the scope of the patented claims, where an "enzymatic composition" of the patented claims 41 and 42 that comprises a phenol oxidase of the patented claims 1 and 2 is indistinguishable from the phenol oxidase of the patented claims 1 and 2.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the applications that matured into the cited patents. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claims 2, 3, and 39-43 are provisionally rejected under the judicially created doctrine of double patenting over claims 9, 11, 61, and 65 of copending Application No. 09/273,957. This is a provisional double patenting rejection since the conflicting claims have not yet been patented. The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: Claims 2, 3, and 39-43 herein describe a phenol oxidase that is a phenol oxidase having an amino acid sequence identical to that *S. chartarum* phenol oxidase described by claims 9, 11, 61, and 65 of the copending application.

Claims 2, 3, and 39-43 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-3 of copending Application No. 10/080,210. This is a provisional double patenting rejection since the conflicting claims have not yet been patented. The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: Claims 2, 3, and 39-43 herein describe a phenol oxidase which is encoded by a nucleic acid sequence capable of hybridizing to SEQ ID NO:1 of the copending application, meeting limitations of claim 1 of the copending application, and describe a phenol oxidase that meets the limitations of

claim 2 and 3 of the copending application, wherein the recombinant production of phenol oxidases in bacterial and yeast host cells is disclosed in the copending application, thus reach phenol oxidases "obtained from" such sources upon recombinant expression.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2 and 39-43 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Claim 3 is not subject to this rejection. The specification fails to exemplify or describe the preparation of the subject matters of the divergent phenol oxidases of claims 2 and 39-43. The rejected claims reach generic proteins that differ at as many as 30% of the amino acid positions of SEQ ID NO:2 according to claims 2, 39, and 43, i.e., at 178 positions overall; at as many 20% of the amino acid positions according to claim 40, i.e., at 119 positions overall; at as many 10% of the amino acid positions according to claim 41, i.e., at 59 positions in all; or at as many 5% of the amino acid positions according to claim 42, i.e., at 30 positions overall. In particular, the specification fails to exemplify or describe the preparation of any phenol oxidase from any of the sources recited in claim 2 except *S. chartarum*, not even a *S. parvispora* phenol oxidase having an amino acid sequence which can meet the limitations of claim 39. Neither the claims nor the specification describe, in any way, where amino acid sequence differences might occur, or what such differences might be, and the specification does not otherwise disclose or suggest the nature or source of any generic phenol oxidase that meets structural limitations of the claims. "While one

does not need to have carried out one's invention before filing a patent application, one does need to be able to describe that invention with particularity" to satisfy the description requirement of the first paragraph of 35 U.S.C. §112. *Fiers v. Revel v. Sugano*, 25 USPQ2d 1601, 1605 (Fed. Cir. 1993). The specification furnishes no relevant identifying characteristics of phenol oxidases that diverges at as many as 178, or 119, or 59, or even 30, amino acid positions from the sequence of SEQ ID NO:2, nor does it provide any characteristic permitting a correlation between undisclosed structures of any protein among the myriad species of generic phenol oxidases of claims 2 and 39-43 and the disclosed amino acid sequences of SEQ ID NO:2.

In addressing the issue of whether a disclosure of a molecular structure of one polypeptide of one biological species could adequately describe the molecular structure of a functionally similar molecule of another biological species, the Court of Appeals for the Federal Circuit held that a claimed invention must be described with such "relevant identifying characteristic[s]" that the public could know that the inventor possessed the invention at the time an application for patent was filed, rather than by a mere "result that one might achieve if one had made that invention". *University of California v. Eli Lilly*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Indeed, the claims rejected herein are, like the claims invalidated by the appellate panel in *University of California v. Eli Lilly*, designed to embrace other, as yet unknown, polypeptides. Nothing demonstrates that, at the time the specification was filed, Applicant was "able to envision" enough of the structure of any of these undisclosed generic proteins to provide the public with identifying "characteristics [that] sufficiently distinguish it . . . from other materials". *Fiers*, 25 USPQ2d at 1604 (citing *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991). The specification's treatment of the claimed subject matter is considered to be entirely prospective where skilled artisans in the relevant field of

molecular biology could not predict the structure, or other properties, of the generic phenol oxidases of claims 2 and 39-43.

Claims 2 and 39-43 are rejected under 35 U.S.C. §112, first paragraph, because the specification is not enabling for any embodiment of human protease having an amino acid sequence that diverges from the amino acid sequences of SEQ ID NO:2 by amino acid substitutions, deletions and insertions, or combinations thereof at as many as 30%, 20%, 10% or even 5% of the amino acid positions of any of SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, make and use the invention commensurate in scope with these claims.

Claim 3 is not subject to this rejection. Claims 2 and 39-43 contemplate an arbitrary assignment of any or all of amino acid substitutions, additions or deletions in a phenol oxidase in as many as 178, or 119, or 59, or even thirty positions in its primary structure. This rejection is stated under the first paragraph of the statute because the specification cannot support unspecified introductions of such numbers of insertions, deletions, or substitutions anywhere, in any combination or any pattern, in the phenol oxidase amino acid sequence set forth in SEQ ID NO:2 that will permit retention of its catalytic activity. Indeed, neither the prior art made of record herewith nor Applicant's specification can identify, taken together, thirty amino acids that might be altered, nor teach the nature of any alteration that may be made, which permits a resulting polypeptide to function as a phenol oxidase. Mere sequence perturbation cannot enable the design and preparation of nucleotide sequences encoding a myriad of divergent protease enzymes and provide the public with a nucleotide sequence encoding an enzyme that retains its native function.

It is well settled that 35 U.S.C. §112, first paragraph, requires that a disclosure be sufficiently enabling to allow one of skill in the art to practice the invention as claimed without undue experimentation and that unpredictability in an attempt to practice a claimed invention is a significant factor supporting a rejection under 35 U.S.C. §112, first paragraph, for non-enablement. See, *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (recognizing and applying the "*Forman*" factors). Cf., *Ex parte Forman*, 230 USPQ

546, 547 (Bd. Pat. App. & Int. 1986) (citing eight factors relevant to analysis of enablement). The standard set by the CCPA, the precursor of the Court of Appeals for the Federal Circuit, is not to "make and screen" any and all possible alterations because a reasonable correlation must exist between the scope asserted in the claimed subject matter and the scope of guidance the specification provides. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 25 (CCPA 1970) (scope of enablement varies inversely with the degree of unpredictability of factors involved in physiological activity of small peptide hormone); see also, *Ex parte Maizel*, 27 USPQ2d 1662, 1665 (Bd. Pat. App. & Int. 1992) (functional equivalency of divergent gene products not supported by disclosure only of a single B-cell growth factor allele). The Federal Circuit approved the standard set by the CCPA in *Genentech, Inc. v. Novo-Nordisk A/S*, 42 USPQ2d 1001 (Fed. Cir. 1997).

The Federal Circuit has also considered whether definitional statements might enable a claim scope argued to extend beyond a disclosed gene product having its native amino acid sequence to embrace a specific variant gene product encoded by a specifically-altered DNA sequence. *Genentech, Inc. v. The Wellcome Found. Ltd.*, 29 F.3d 1555, 31 USPQ2d 1161 (Fed. Cir. 1994). The court held that only a narrow structural and functional definition was enabling precisely because the sweeping definitions of scope in the patent specification could not reasonably have been relied upon by the PTO in issuing the patent. *Genentech*, 29 F.3d 15 at 1564-65, 31 USPQ2d at 1168. Applying the "*Forman*" factors discussed in *Wands, supra*, to Applicant's disclosure, it is apparent that:

a) the specification lacks adequate, specific, guidance for altering the amino acid sequences of the phenol oxidase of SEQ ID NO:2 to the extent recited in any of claims 39-43,

b) the specification lacks working examples wherein the phenol oxidase of SEQ ID NO:2, is altered to the extent recited in any of claims 39-43,

c) in view of the prior art publications of record herein, the state of the art and level of skill in the art do not support such alteration, and,

d) unpredictability exists in the art where no members of the class of phenol oxidase represented by the amino acid sequence of SEQ ID NO:2, have had as many as thirty amino acids specifically identified for concurrent modification.

Thus the scope of subject matters embraced by the phrases, "having at least 70% [or 80%, or 90%, or 95%] identity to", is unsupported by the present specification even if taken in combination with teachings available in the prior art.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. §102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. §122(b). Therefore, this application is examined under 35 U.S.C. §102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. §102(e)).

Claims 2, 3, and 39-43 are rejected under 35 U.S.C. §102(b) as being anticipated by Convents et al., WO 99/49010, who disclose, Figure 5, the amino acid sequence of a *Stachybotrys* phenol oxidase that meets the limitations of claims 2, 3, and 39-43 herein.

Claims 2, 3, and 39-43 are rejected under 35 U.S.C. §102(b) as being anticipated by Amory et al., WO 99/49020, who disclose, Figures 5A and 5B, the amino acid sequence of a *Stachybotrys* phenol oxidase that meets the limitations of claims 2, 3, and 39-43 herein.

Claims 2, 3, and 39-43 are rejected under 35 U.S.C. §102(b) as being anticipated by Wang et al., WO 00/37654, an entity that differs from the inventor named herein,

who disclose, Figures 5A and 5B, the amino acid sequence of a *Stachybotrys* phenol oxidase that meets the limitations of claims 2, 3, and 39-43 herein.

Claims 2, 3, and 39-43 are rejected under 35 U.S.C. §102(b) as being anticipated by Bodie et al., WO 00/39306, who disclose, Figures 5A and 5B, the amino acid sequence of a *Stachybotrys* phenol oxidase that meets the limitations of claims 2, 3, and 39-43 herein.

Claims 2, 3, and 39-43 are rejected under 35 U.S.C. §102(e) as being anticipated by Wang et al., U.S. Patent No. 6,399,329, an entity that differs from the inventor named herein, who disclose, Figures 5A and 5B, the amino acid sequence of a *Stachybotrys* phenol oxidase that meets the limitations of claims 2, 3, and 39-43 herein.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 703.308.0583. The examiner can normally be reached from 9:00AM-5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached at 703.308.3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703.308.4242 for regular communications and 703.308.0294 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0196.

William W. Moore
July 10, 2003